REMARKS

This amendment is responsive to the Final rejection of February 28, 2008, including new grounds of rejection of the claims as containing new matter. This ground of rejection could not have been addressed earlier.

Claims 1-13, 18-19, 21-22, and 24 have been cancelled. Claims 14, 20, 23, 25, and 26 have been amended. Claims 14-17, 20, 23, and 25-26 are now pending in this application. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Rejection under 35 U.S.C. § 112, first paragraph – written description

Claims 20-22 and 26 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time that the application was filed.

This ground of rejection is moot with regards to claims 21-22 which have been canceled.

This ground of rejection is addressed by amendment. Claims 20 and 26 have been amended to recite "a peptide consisting of the amino acid sequence shown as SEQ ID NO: 2 and/or a peptide consisting of the amino acid sequence shown as SEQ ID NO: 3". The claims are limited to the specified sequences.

In view of Applicants' amendment, withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a)

Claims 14-22 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Iigo, et al. (Clinical and Experimental Metastasis 17: 35 (1999)) in view of Yoo, et al. (Jpn. J. Cancer Res. 88: 184 (1997)), WO 00/12542, JP2000-229881 and Applicants' admission on page 2, lines 3-13 of the specification.

Applicants gratefully acknowledge withdrawal of this ground of rejection for claims 23, 25, and 26. This ground of rejection is addressed in part by amendment and in part by arguments as discussed below.

Claims 14 and 20 have been amended to recite that the drug composition is directed to a cancer "having resistance to the antibody drug" and to specify "anti-CD20 antibody". Support is found in canceled claims 18, 19, 21, and 22. The present claims are now limited to anti-CD20 antibody, which is exemplified in the specification (present specification, page 28, last line).

A drug composition of the presently claimed invention is a drug for antibody therapy of cancer having resistance to the antibody drug, which comprises a lactoferrin hydrolysate, anti-CD20 antibody, and complement, all as active ingredients.

In contrast, the drug of Iigo, et al. is a drug composition for inhibition of tumor growth in lung and colon cancers in mice which comprises a bovine lactoferrin, bovine lactoferrin hydrolysate, and peptide lactoferricin in combination with an antibody (antiasialoGM1). While Iigo, et al. disclose drug compositions that inhibit tumor growth in lung and colon cancers, Iigo, et al. do not teach or suggest a drug which comprises a lactoferrin hydrolysate, anti-CD20 antibody and complement which has enhanced cytotoxic activity against cells which show resistance to the cytotoxic activity of complement and antibody, as exemplified in Table 4 of the present specification. Accordingly, the claimed drug compositions are not taught or suggested by Iigo, et al.

Applicants believe that they have found for the first time that a drug composition comprising a lactoferrin hydrolysate, anti-CD20 antibody and complement can exert enhanced cytotoxic activity against cells resistant to the cytotoxic activity of the antibody. The deficiencies of Iigo, et al. are not corrected by the secondary references, alone or in combination.

In view of Applicants' arguments and amendments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Rejection under 35 U.S.C. § 112, first paragraph - New Matter

Claims 14-23 and 25-26 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time that the application was filed.

The Examiner states that the sections cited by Applicants do not support the use of "a complement".

This ground of rejection is addressed by amendment and by argument.

Applicants have amended "a complement" to "complement".

The combination of antibody and complement is supported throughout the specification. The Examiner states that the sections referred to (page 6, line 8; page 10, 3rd line from bottom; page 13, first full paragraph; Test Examples 1-5) do not provide support for complement added as part of the drug (Office Action, page 10, last paragraph).

In response, the passage at page 13 teaches "enhancing an activity of a complement and/or an antibody drug" which unambiguously teaches the combination of an antibody drug AND complement. The test method on page 29 also describes the experimental design to include a treatment of antibody + complement as also shown in Tables 1-3.

With regards to the complement used, the Examiner doubts that the human serum AB from Cosmobio referred to on page 29 of the specification contains any complement proteins and asserts that there is not "objective evidence of record to show that human serum AB contains the complement proteins" (Office Action, page 10).

Applicants respond that it is very well known in the art to use a human serum in order to investigate a complement-dependent cytotoxic activity of an antibody as shown by page 44, lines 28-29 of WO 94/11026, attached here as Attachment A. Further, as shown in page 2 , line 25 to page 3, line 2 of WO92/07466 (Attachment B), it is known to use human serum as a source of complement to kill tumor cells in combination with antibody. The Attachments provide objective evidence for human serum as containing complement proteins.

The Examiner further states that "even if human serum AB contains the complement proteins, applicant's claims states "a complement" meaning only one complement protein"

(Office Action, pages 10-11, bridging sentence). This has been addressed by amendment of the claims throughout to replace "a complement" with "complement".

In view of Applicants' amendments, arguments and Attachments A and B, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 14-23 and 25-26 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The term "a complement" has been amended to "complement".

b. Claims 20 and 26 have been amended to improve clarity.

In view of Applicants' amendments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the

application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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